Effect of trunnion roughness and length on the modular taper junction strength under typical intraoperative assembly forces

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Abstract

Modular hip implants are at risk of fretting-induced postoperative complications most likely initiated by micromotion between adjacent implant components. A stable fixation between ball head and stem-neck taper is critical to avoid excessive interface motions. Therefore, the aim of this study was to identify the effect of trunnion roughness and length on the modular taper strength under typical intraoperative assembly forces.

Custom-made Titanium trunnions (standard/mini taper, smooth/grooved surface finish) were assembled with modular Cobalt-chromium heads by impaction with peak forces ranging from 2 kN to 6 kN. After each assembly process these were disassembled with a materials testing machine to detect the pull-off force as a measure for the taper strength.

As expected, the pull-off forces increased with rising peak assembly force ($p<0.001$). For low and moderate assembly forces, smooth standard tapers offered higher pull-off forces compared to grooved tapers ($p<0.038$). In the case of an assembly force of 2 kN, mini tapers showed a higher taper strength than standard ones ($p=0.037$).

The results of this study showed that smooth tapers provided a higher strength for taper junctions. This higher taper strength may reduce the risk of fretting-related complications especially in the most common range of intraoperative assembly forces.

199 words (max. 200 words)

1. Introduction

Modular hip prostheses are commonly used in operation routines of total hip replacements and offer at least one conical taper junction connecting the femoral stem-neck with the ball head. This concept was established in the 1970s to allow surgeons more flexibility in the choice of head material and diameters, and head-stem offsets for a more individualised anatomical reconstruction of the patient's hip joint [1] while retaining the femoral stem and to substantially reduce the inventory [2]. It was assumed that due to an optimized positioning of the artificial joint the revision rates could be decreased. However, the latest clinical data do not reflect the desired positive effects [3–6] with revision rates of up to 86 % for a double-tapered modular hip prosthesis after a follow-up time of less than five years [4]. In recent years concerns have arisen regarding fretting [7,8], wear [9,10] and corrosion at modular taper junctions [8,9,11–15] further increasing the number of revision surgeries [5,8,9,12,16]. The resulting postoperative complications include, but are not limited to, pain [7,13,17], soft tissue damage [7,11], the formation of pseudotumours [7,15,18,19] and osteolysis [20,21] and are frequently associated with high metal ion levels in the blood and/ or urine [15,22–24]. Despite the fact that the precise failure mechanism at taper interfaces is not yet completely elucidated, it is undisputed that micromotion between the adjacent implant components plays a role for this clinical concern [9,25–28]. Previous experimental [28–33] and numerical studies [34,35] have evaluated micromotion at taper interfaces: the documented values report a large range from a few microns to more than 40 μm indicating that several factors such as, the prosthesis geometry, manufacturing tolerances of the taper, the location of the taper connection (head-stem or stem-neck), taper surface topography and the assembly conditions may influence the micromotion levels [28–32,35]. These may be linked to changes in the location and size of the taper contact area [36] and the assembly force. Taper junctions are exposed to high bending and torsional loads during daily activities supporting the occurrence of micromotion. These can provoke mechanical, as well as electrochemical initiated, processes in the fluid environment of the hip joint leading firstly, to fretting [27,37,38] and mechanically assisted crevice corrosion [9,14,16,39] and secondly, to a cascade of adverse local tissue responses [5,13,40] in the form of pseudotumours [18,19,39,15], allergic reactions and middle to high grade tissue damage [11,15]. The material susceptibility to fretting and corrosion seems to be an important factor in the failure mechanism as well. However, no consistent consensus currently exists either for similar or for mixed material couplings [16,25,27,37,38]. Fretting-induced postoperative complications were first reported in significant numbers for large diameter metal-on-metal hip joint articulations [11,41–43] and these device designs appear to negatively enhance taper issues due to higher friction moments at the interface especially in case of low lubrication [44]. Besides fretting-induced complications, an insufficient taper strength caused, for example, by an inadequate intraoperative assembly, may also provoke a loosening of the taper connection [11]. Cases of disassembly of the ball head after dislocation [45,46] or during closed reduction of a dislocated femoral component [47,48] have also been observed in clinical applications.

The current state-of-the-art implies that a firm and permanent fixation of the implant components is critical to minimize postoperative issues [10,16,25,49,50]. Although this fact is well known, explicit guidelines to assemble the implant components are currently rarely available in manufacturer's operative procedure guidelines [51–53]. Moreover, those handling instructions, for example, describing the procedure to assemble a ball head onto a stem taper, are kept very vague [51–53]. It is hypothesised that design-, implantation- and surgeon specific parameters may influence the risk of excessive interface motions and subsequently fretting and corrosion due to inadequate assembly and fixation of these modular implants.

Therefore, the aim of this study was to determine the effect of taper surface roughness and length on the stem-head taper junction strength under typical intraoperative assembly forces.

2. Materials and methods

2.1. Materials, profilometry and assembly

Three groups of titanium custom-made trunnions (Figure 1A, Ti6Al4V alloy, ASTM F136, in total n = 15, Corin Group PLC, Cirencester, UK) with a 12/14 conical taper connection, different taper lengths and surface finishes were used for mechanical testing: smooth, standard tapers (Group 1) vs. grooved, standard tapers (Group 2) vs. grooved, mini tapers (Group 3). The taper length of the mini tapers was approximately 6.5 mm shorter compared to the standard tapers (14.5 mm) while retaining the taper size (maximum cone diameter 14 mm). Prior to the assembly, the taper surfaces were cleaned with ethanol to remove any potential surface contamination and the profile of the stem tapers' outer surface was scanned with a contactless, high-resolution, three-dimensional measurement instrument (ProScan2000 Surface Profilometer, Scantron Industrial Products Ltd, Taunton, UK). Two different surface areas were scanned per test sample with a scan area of 1 mm^2 and a step size of 0.002 mm in both directions each. Based on the scans, the average roughness values Rz and Ra were determined for each trunnion. Additionally, the taper interface of the ball heads and trunnions were helically scanned with a coordinate measuring machine using a ruby stylus for digitisation of the geometry (Incise, Renishaw, Gloucestershire, UK, Figure 1B and C). The surface profiling was primarily used to determine the taper angles and to estimate the location of the press-fit and the contact area (Figure 1B and C). The data sets were analysed using a custom script (MATLAB R2011b; MathWorks, Natick, MA, USA). The centre of mass for each helix was determined allowing the identification of the taper axis that was used as a basis for a subsequent best-fit algorithm. Due to a very robust algorithm, the proximal plane of the trunnions' and the ball heads' plane at the open end, respectively, did not have to be aligned absolutely horizontally during scanning, an angle deviation of up to 3° was acceptable. Based on the outcome of this analysis, the taper angle difference, defined as the angle of the head subtracted by the angle of the trunnion, was calculated (Figure 1B). The components were then assembled at ambient environmental conditions with a 28 mm cobalt-chromium ball head (LC-CoCr29Mo alloy, ASTM F1537, size L) by an impaction using a previously described custom-made drop-rig [54] to mimic the intraoperative procedure. The drop tower consisted of two vertical sliders guiding a horizontal beam with a drop weight attached (total mass 2.4 kg). The drop weight was capped with a nylon disc to reduce the risk of multiple impactions due to a rebound effect. The drop rig was pre-calibrated in order to identify the relationship between drop height and peak assembly force. Based on the simulated peak assembly force the drop height ranged between 22 mm and around 60 mm. Each trunnion-head pair was consecutively assembled along the taper axis with different peak forces ranging from 2 kN to 6 kN (sequence of assembly: $F_1 = 2$ kN, $F_2 = 2$ kN, $F_3 = 4$ kN, $F_4 = 2$ kN, $F_5 = 6$ kN, $F_6 = 2$ kN). The assembly forces were chosen in alignment with typical intraoperative forces [55,56].

2.2. Disassembly and statistics

After each assembly process the implant components were disassembled using a materials testing machine (Series 5965, Instron, Norwood, MA, USA) to measure the pull-off force as an indicator for the taper strength (Figure 2). The trunnions were rigidly attached to the testing machine base and almost the complete ball head was enclosed by a second fixture that was directly coupled to the materials testing machine's actuator and the axial load cell (Figure 2). According to ISO 7206-10: 2003 the pull-off tests were performed at a stroke rate of 0.008 mm/s with a data acquisition rate of 10 Hz. In order to ensure that the pull-off forces were not influenced by the consecutive test protocol, the results of all of the 2 kN tests were statistically compared. The average pull-off force for each sample at a load level of 2 kN (F_1, F_2, F_4, F_6) was calculated and then used for the following analyses to keep the sample size for the assembly load levels constant ($n = 15$).

For statistical analyses non-parametric and parametric tests with a type-I-error probability of $\alpha = 0.05$ were performed (SPSS Statistics 20, Munich, Germany). For further correlation analyses, the pull-off forces were z-standardized leading to a variable's mean of zero and a standard deviation of one. Correlations between two metric variables were assessed using linear regression.

3. Results

3.1. Profilometry & taper angles

The trunnion surface showed a regular shaped pattern similar to a wave profile with a groove depth of approximately 15.5 µm (grooved)/ 7.5 µm (smooth) and a groove spacing of around 300 µm (grooved) and 150 µm (smooth), respectively (Figure 3). Independent of the taper length, grooved tapers had significantly higher roughness values in terms of both Rz (16.76 ± 0.57 µm vs. 7.97 ± 1.45 µm, $p = 0.001$, Mann-Whitney U) and Ra (4.14 ± 0.54 µm vs. 2.92 ± 0.44 µm, $p = 0.003$, Mann-Whitney U) in z-axis than those with a smooth surface finish (Figure 3). The ball heads exhibited on average a taper angle of 5.67 ± 0.05° leading to a mean taper angle mismatch for standard trunnions of 0.10 ± 0.05°. Since both, the standard and the mini tapers, exhibited a 12/14 taper connection, the taper angles of the mini tapers were larger compared to the standard tapers resulting in a taper angle mismatch of approximately zero (- 0.03 ± 0.02°).

3.2. Pull-off forces

For all of the performed mechanical tests, the consecutive testing of the implant components did not influence the pull-off forces at the trunnion-head interface ($0.216 \leq p \leq 0.922$, Kruskal-Wallis / one way ANOVA). Overall, independent of the taper length and the surface finish, the recorded pull-off forces were on average 24.9 % (± 9.3%) of the assembly force. For both surface modifications, the pull-off force of standard tapers increased significantly with rising peak assembly force (Group 1 & 2, 2 kN: 0.549 ± 0.084 kN vs. 4 kN: 0.954 ± 0.101 kN vs. 6 kN: 1.436 ± 0.145 kN, $p < 0.001$, two way ANOVA, Figure 4). For assembly forces of 4 kN or less, standard stem tapers with a smooth surface finish had significantly higher pull-off forces compared to those with a grooved surface (Group 1 & 2, 0.820 ± 0.239 kN vs. 0.684 ± 0.202 kN, $p < 0.001$, two way ANOVA, Figure 4). Following a 6 kN impaction, no influence of the surface finish on the pull-off force was detected (Group 1 & 2, 1.435 ± 0.145 kN, $p = 0.426$, one way ANOVA, Figure 4). Similar to the standard tapers, a positive correlation between assembly and pull-off force was also determined for the mini tapers (Group 3, linear regression, adj. $R^2 = 0.804$, $p < 0.001$). Only in case of an assembly force of 2 kN, grooved mini tapers exhibited a significantly higher taper strength compared to grooved standard tapers (Group 2 & 3, 0.630 ± 0.113 kN vs. 0.497 ± 0.041 kN, $p = 0.037$). However, with rising assembly force this effect became smaller and smaller: at 4 kN still a trend was observed (Group 2 & 3, $p = 0.065$, Welch Test) whereas for the highest assembly force of 6 kN no effect could be found anymore (Group 2 & 3, $p = 0.266$, one way ANOVA, Figure 4). Independent of the assembly force, for the standard tapers a significant influence of the taper angle mismatch on the taper junction strength was not observed (Group 1 & 2, $0.403 \leq p \leq 0.990$, linear regression). In contrast, the pull-off forces of the mini tapers tended to increase with decreasing angular mismatch in the assessed range of -0.05° to -0.01° for all assembly forces (Group 3, $0.022 \leq p \leq 0.093$, linear regression). Z-standardized pull-off forces of mini tapers showed a significant negative correlation with the taper angle difference (Group 3, adj. $R^2 = 0.718$; $p < 0.001$, Figure 5).

4. Discussion

Fretting-induced postoperative complications of modular hip prostheses have become a serious problem in total hip arthroplasty [57]. Micromotion between adjacent implant components appears to be critical for this clinical concern [9,25–28]. In combination with fluid ingress into crevices resulting from angular differences of adjacent implant components or an insufficient taper fixation, this may lead to fretting and/ or corrosion [9,16,27,37–39,15], dramatically limiting the functional life of a hip replacement [3–6,28]. Additionally, misalignments and even a complete disassembly of a prosthesis component can be caused under adverse circumstances by an insufficient taper strength [45–48]. Although these clinical problems are well documented, no explicit instructional guidelines to assemble the implant components are provided for most of the implants available on the market. Since the importance of a stable, rigid connection of taper junctions has been identified [10,16,25,49], this experimental study focused on the impact of trunnion roughness and length on the taper junction's strength under typical intraoperative assembly forces.

In the presented study only one taper design with a 12/14 taper was assessed with one specific material coupling (Ti - CoCr). This fact may limit the transferability of the results to other designs and/or material combinations. Due to differences in the taper geometry of cobalt-chromium and ceramic ball heads, it is expected that the location of the press-fit, the size of the contact area and the prevalent contact pressure will be different for the two materials. The taper angle of ceramic ball heads is usually higher compared to metal heads suggesting that the press-fit area is located nearer to the closed end of the taper connection. Therefore, a general statement on the effect of the assessed influencing parameters cannot be easily drawn without any further investigations. For the assembly process a custom-made drop tower was used which utilised a plastic cap at the impactor's end. This scenario does not represent the clinical situation in which the implant components were usually assembled by one or more metal hammer blows. Due to the plastic end cap, the applied kinetic energy was reduced compared to a metal-on-metal blow as a consequence of a damping effect. This study is furthermore limited by assessing the surface topography of the trunnions only, as the profilometer measurements of the head female tapers could not be made because of the nature of the profilometer used in this study. The initial contact situation at the stem-head taper directly after assembly was evaluated, rather than the assessment of changes in taper strength due to any subsequent dynamic loading that may mimic the usual daily activity of a patient. Thus, due to this lack of dynamic loading, potential interface micromotions were not recorded.

The surface topography of the tapers used in this experimental study was comparable to threaded taper designs available on the market [17,58]; they offered a repetitive distinct surface pattern with a specific groove height and spacing between two adjacent threads. The rough tapers showed an average maximum profile height (Rz) comparable to the Profemur (Wright Medical), Synergy (Smith and Nephew), Summit and Corail (DePuy Synthes) prosthesis with values between 16.02 µm and 17.38 µm, however, their average roughness (Ra) was lower (4.14 µm vs. 2.23 - 3.35 µm) [58]. The groove depth of the clinically used threaded designs is smaller compared to the rough tapers (7.24 - 13.49 µm vs. ≈ 15.5 µm) [58]. The roughness value Ra of the smooth tapers was comparable to the clinically used ones named before as well as to the Trilock and Silent stem tapers (DePuy Synthes, 2.09 - 2.83 µm vs. 2.92 ± 0.44), whereas, Rz conformed to the Secure-fit Max threaded design (Stryker, 7.23 µm) and the non-threaded designs ABG II (Stryker), Taper-lock (Zimmer), Accolade (Stryker) and SROM (DePuy Synthes, 6.1 - 7.5 µm) [58]. It should be noted, that the test method used to determine the surface topography of the tapers deviated from the one applied by Munir et al. [58]. In the present study only 2D characteristics were assessed, whereas Munir et al. used an interference microscope and a post-processing step to determine 3D topographical surface features as well.

This experimental study clearly demonstrated that the taper length and the surface roughness can significantly influence the taper junction strength predominantly in the most common range of intraoperative assembly forces. As expected and in agreement with other studies, the pull-off forces increased significantly with rising peak assembly force [50,59–62]. A doubling of the assembly force resulted in a 1.7 times higher pull-off force whereas a tripling gave rise to a 2.6-fold increase of the taper strength. Rehmer et al., MacLeod et al. and Ihesiulor et al. found a significant higher mean pull-off force/ assembly force ratio (25% vs. 33 - 67%) compared to this study [50,61,63]: possible reasons may be differences in the topography and roughness of the taper surfaces, the taper length and head size leading to discrepancies in the location of the interlock and the contact force. Additionally, varying assembly procedures (dynamic vs. static) and rigs, disassembly test speeds as well as different material combinations may also have played a role [50,61,63]. The prosthesis design also affects the taper junction strength and its variability substantially [59]. The taper angle mismatch is suspected to be of considerable importance as well [60]. A correlation between head size and taper strength has already been found [61]: 36 mm metal heads exhibited a significantly lower pull-off force compared to 28 mm ones when impacted with peak forces of 5 kN or less. This finding has been associated with the high failures rates in large diameter hip replacements [61]. Previous studies reported an increased seating of the head on the stem taper (primary seating) for high assembly forces [33,62]. This seems to result in a more favourable taper contact situation with a high contact pressure in the stem-head interfaces associated with the observed improved taper strength [62] and a reduction in micromotion [33].

Following an impaction of 4 kN or less, smooth standard tapers exhibited a higher taper strength, most probably due to a more favourable contact situation. The spacing between two adjacent grooves and their depths is much smaller for the smooth surface finish compared to the grooved tapers. Only in case of high assembly loads, small local plastic deformations of the grooves are expected suggesting an increasing contact area comparable to smooth tapers. Witt et al. found a significant increase in the area and the number of ridges being in contact with rising assembly force [36]. In a similar manner, Fallahnezhad et al. determined in their FE-Analysis an increasing contact length and pressure with rising assembly force, whereas the contact length of CoCr/Ti couplings was always larger compared to CoCr/ CoCr junctions [60]. Furthermore, a positive correlation between assembly force and the amount of permanent plastic deformation has been reported [36]. Besides the reduced taper strength of rough tapers following a slight or moderate impaction, these tapers seem to be also more susceptible to fretting than smooth tapers [64]. Furthermore, a positive correlation between taper surface roughness (Rpk) and wear rates has been reported [17]. In an in vitro study, Panagiotidou et al. found a noticeable rupture of the oxide film during dynamic loading at a modular Ti/ CoCr junction with a rough surface profile, whereas the fretting and corrosion damage for a smooth taper was marginal [64].

Discrepancies in the taper strength between standard and mini tapers following a light hammer blow may also be traced back to differences in the contact area and contact pressure. As expected and in alignment with a FE-Analysis, the contact of standard tapers occurs proximally (closed end of taper connection) due to a positive angular mismatch [60,65], in contrast to mini tapers with a mismatch of almost zero and therefore an unpredictable location of the area being in contact (proximal, distal or across the whole taper length). This statement is in agreement with a previously published study: Witt et al. found out that the location of the damaged area is irregularly distributed along the whole taper surface in case of a small taper angle difference [36]. Cook et al. expects an influence of the angular mismatch within the stem-head taper connection on the generation of wear particle [10]. However, Kocagoz et al. could not confirm a direct correlation between angular mismatch and wear and corrosion scores [65]. But, the angular mismatch seems to be inversely correlated with the amount of interface micromotions [33].

It is speculated that the intraoperative assembly procedure has a significant influence on the initial contact situation [60] and subsequently a big influence for the clinical performance. In addition to the assembly force, impaction angle, the number of impactions and the instrumentation tool, the presence of contaminants in the interface due to an insufficient cleaning is also considered as potentially critical. An inadequate assembly associated with the impact not aligned axially may increase the presence of crevices within conical taper connections, allowing fluid ingress and ultimately the creation of corrosion. During surgery some surgeons assemble the modular components by multiple impactions and under different conditions i.e. wet or dry. It has been shown, that the impact force of the first hammer blow is the most important one with regard to the taper strength [50,59]. The assembly force sequence in case of multiple impactions [59] and the taper condition prior to the assembly (wet or dry) may also change the pull-off forces either in a positive or negative way, depending on the prosthesis design [59]. The presence of bone chips contaminating the tapers can exhibit interface micromotions more than double that compared to clean tapers [30]. Weisse et al. demonstrated, that contaminants such as bone chips, tissue or blood in the stem-head taper interface can reduce the static fracture load of ceramic ball heads by up to 90% compared to non-contaminated interfaces [66]. It should furthermore be considered that, depending on the surgical approach chosen, a dynamic assembly of the stem-head taper junction with a hammer or a head impactor can be excessively difficult or impossible. It can also be speculated that the tapers cannot be easily cleaned to remove any contaminants in the interface prior to the assembly [57]. To the authors' knowledge there are currently no data available implying that the number of fretting complications directly correlates to a specific surgical approach. This suggests that not only the assembly force and condition (wet or dry) but rather several factors affecting the risk of fretting e.g. the taper design, angular mismatch, head diameter and the used materials. Nevertheless, for further developments of modular components this issue needs to be adequately addressed.

Although there are currently no data available confirming that a high taper strength is directly linked with a reduced risk of fretting complications, it seems to be highly probable that this hypothesis is true. Fretting can only occur if there are crevices present, which allow fluid ingress [27]. In case of a high taper strength accompanied with an extremely high contact pressure the crevices within the taper junction may be negligibly small avoiding fluid ingress and preventing the initiation of corrosion. A few experimental in vitro studies have already assessed the influence of assembly load, axial load and assembly condition (wet vs. dry), respectively, on the onset of fretting. Goldberg et al. and Mroczkowski et al. assessed the fretting corrosion behaviour using an in vitro electrochemical test set-up [27,49]. The open circuit potential (OCP) decreased with rising cyclic load whereas the fretting current increased. This can be seen as a result of a removal of the oxide film and a subsequent repassivation within the taper connection [49]. The force threshold to initiate taper fretting is significantly higher for implants assembled with a strong impaction (6.7 - 8.0 kN) in air (onset at a load of ≈ 2.5 kN [49]) than those pressed only by hand (for wet and dry condition, onset at a load less than 0.5 kN [49]) or statically assembled with 2.0 kN (onset at a load less than 1.3 kN [27]). However, during daily living activities, modular taper connections are not only exposed to pure axial loads but rather to a combination of axial and rotational loads. In addition, a positive correlation between assembly force and the minimum torque required to initiate fretting processes in the interface has already been reported [54]. The determined values for load and torque at the onset of fretting can easily be reached during daily living activities [27,54]. Baxmann et al. showed with an in-vitro fretting test system that fretting wear with indications of particle detachment can occur in case of a low contact pressure (normal load ≤ 50N) combined with high interface motions (≥ 25N) [67]. Chu et al. found out in their FE Analysis that a separation of contact in the taper connection can cause wear and corrosion [68]. Based on the current knowledge, a correlation between taper strength and fretting damage seems possible but cannot be directly deduced.

As already mentioned by MacLeod et al., the initial contact situation directly after the assembly procedure does not permit direct conclusions on the long-term performance [61]. Nevertheless, the taper strength may be one of several contributors to estimate the risk of fretting.

5. Conclusions

This study has demonstrated that trunnion-specific parameters as well as the assembly force have a significant impact on the stem-head taper strength. High assembly forces gave rise to a greater pull-off force; this may decrease the interface micromotions and ultimately the risk of fretting and wear. Nevertheless, it should be considered that an excessively high hammer blow may provoke damage to the bony structure and/or the surrounding tissue during surgical assembly. Therefore, an assembly force of around 4 kN appears to be a reasonable compromise in agreement with the previous recommendation made by Rehmer et al. [50] and Haschke et al. [33].

An important finding is that smooth tapers are more appropriate to use in taper connections with modular metal heads in the future since these tapers offer a higher taper strength, especially, in the most common range of intraoperative assembly forces. It is furthermore suspected, that rough tapers are more susceptible to fretting than smooth ones [64]. The results also indicate that mini tapers can exhibit comparable taper strength to those of standard tapers even if they offer an overall smaller taper surface area. There is thus evidence that it is not the overall taper surface area that is essential, but rather the actual taper contact area, which is affected by, but not limited to the surface topography, taper angle mismatch and the assembly force.

Ethical approval

Not required.

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Conflict of interest statement

All authors do not have any conflicts of interest that are related to this study, to disclose.

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